

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

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| Sheet | 1 | of | 2 |
|-------|---|----|---|

Complete if Known

| | |
|------------------------|-----------------------|
| Application Number | Unassigned |
| Filing Date | Concurrently Herewith |
| First Named Inventor | Michael W. DAHM |
| Group Art Unit | Unassigned |
| Examiner Name | Unassigned |
| Attorney Docket Number | 24741-1538 |

[illegible][illegible]

**Examiner
Signature**

/Anne Gussow/

Date Considered

02/12/2007

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

10/524544

Please type a plus sign (+) inside this box ☒ PTO/SB/08A (08-00)

105 Rev. 10/1/00 14 FEB 2005

Approved for use through 10/31/2002. OMB 0851-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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| Group Art Unit | Unassigned |
| Examiner Name | Unassigned |
| Attorney Docket Number | 24741-1538 |

Sheet 2 of 2

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|---------------------|-----------------------|---|----------------|
| AMG | A05 | HEXAL GENTECH FORSCHUNGS-GMBH: ONCOQUICK-TM GEBRAUCHSANLEITUNG, Online!; greiner bio-one, oncoQuick Instruction Manual, http://www.hexal-gentech.de/products/man_d.pdf , XP002261835 | |
| | A06 | ALEXANDER GOETZ, "Mit OncoQuick den Metastasen auf der Spur, BIOFORUM, p. 394, 2001. Vol. 24, GFT VERLAG GMBH, DARMSTADT, XP002261836 | |
| AMG | A07 | ALEXANDER W. GOETZ et al., "Enrichment of disseminated breast cancer cells from human peripheral blood by advanced density gradient centrifugation", Proceedings of the American Association for Cancer Research Annual Meeting, March 2002, p. 733, Vol. 43, XP002261837 | |
| AMG | A08 | J. BISCHOFF et al., "Detection of disseminated tumor cells in bone marrow and peripheral blood of patients with metastatic breast cancer", Annual Meeting of the American Society of Clinical Oncology, May 2002, XP002261838 | |
| AMG | A09 | R. ROSENBERG et al., "Comparison of Two Density Gradient Centrifugation Systems for the Enrichment of Disseminated Tumor Cells in Blood", Cytometry, December 1, 2002, pp. 150-158, Vol. 49, No. 4 | |
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Examiner
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/Anne Gussow/

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No: 029368.00003 (formerly 24741-1538)

Confirmation No.: 1428

In re patent application of:
Michael W. DAHM

Group Art Unit: 1643

Serial No.: 10/524,544

Filed: February 14, 2005

Examiner: GUSSOW, Anne

For: METHOD FOR THE IMMUNOCYTOLOGICAL OR MOLECULAR DETECTION
OF DISSEMINATED TUMOR CELLS FROM A BODY FLUID AND KIT THAT IS
SUITABLE THEREFOR

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Date: June 1, 2007

Sir:

Pursuant to 37 CFR §1.56, the attention of the U.S. Patent and Trademark Office is hereby directed to the information items listed on the attached PTO/SB/08. Unless otherwise indicated herein, one copy of each item is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the items be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

☐ 1. This Information Disclosure Statement is being filed (a) within three months of the U.S. filing date, OR (b) before the mailing date of a first Office Action on the merits in the present application, OR (c) accompanies a Request for Continued Examination. No certification or fee is required.

☒ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.

☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).

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☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual

designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).

- ☒ c. Check in the amount of \$180.00 is attached for payment of the fee under 37 CFR §1.17(p). Please charge any fee deficiency or credit any overpayment to Deposit Account Number 01-2300, referencing Attorney Docket Number 029368.00003, as needed to ensure consideration of the disclosed information.
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Applicants hereby petition that the Information Disclosure Statement be considered. Attached is our check number _____ in the amount of \$180.00 for payment of the petition fee under 37 CFR §1.17(i)(1). Please charge any fee deficiency or credit any overpayment to Deposit Account Number 01-2300, referencing Attorney Docket Number _____, as needed to ensure consideration of the disclosed information.
- ☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).
- ☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).
- ☒ 4. The relevance of the cited references is discussed in the Amendment and Reply Under 37 C.F.R. § 1.111 submitted herewith. The B02 reference shows the application of OncoQuick® to separate tumor cells from non-tumor cells in blood samples. A translation of the Abstract is attached.

Respectfully submitted,



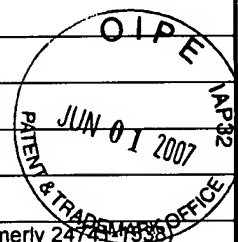
Patricia D. Granados
Registration Number 33,683

Customer Number 004372
ARENT FOX LLP
1050 Connecticut Avenue, NW
Suite 400
Washington, DC 20036-5339
Telephone: 202-857-6000
Fax: 202-857-6395
PDG:knc
Enclosure: PTO/SB/08a

TECH/516234.1

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|---|---|----|---|------------------------|------------------------------------|
| Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Application Number | 10/524,544 |
| | | | | Filing Date | February 14, 2005 |
| | | | | First Named Inventor | Michael W. DAHM |
| | | | | Art Unit | 1643 |
| | | | | Examiner Name | GUSSOW, Anne |
| Sheet | 1 | of | 1 | Attorney Docket Number | 029368.00003 (formerly 24741.1538) |



NON PATENT LITERATURE DOCUMENTS

| Examiner initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|-------------------|-----------------------|---|----------------|
| | B02 | GOETZ, Alexander, "Mit OncoQuick den Metastasen auf der Spur", BIOforum forschung und entwicklung, p. 394, 2001, Vol. 24, XP-002261836, GIT VERLAG GMBH, Darmstadt, Germany | |
| | B03 | English language translation of Abstract paragraph for Goetz article "Mit OncoQuick den Metastasen auf der Spur", BIOforum forschung und entwicklung, 24 (201) 394. | |
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| Examiner Signature | | Date Considered | |
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This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P. O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

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